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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,805	03/18/2004	Gennady V. Merkulov	CL001186DIV-II	6122

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,805	MERKULOV ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐. This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending and are subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 20-21, drawn to a polypeptide of SEQ ID NO:2 and its variants and fragments, classified in class 435, subclass 198.

II. Claim 3, drawn to antibody against the lipase, classified in class 530, subclass 387.9.

III. Claims 4-11 and 22-23, drawn to DNA encoding SEQ ID NO:2, vector comprising said DNA, host cell comprising thereof and a method of producing polypeptide, classified in class 435, subclass 198.

IV. Claim 12, drawn to a method of detecting the presence of the polypeptide, classified in class 435, subclass 26.

V. Claim 13, drawn to a method of detecting the presence of the polynucleotide, classified in class 435, subclass 6.

VI. Claim 14, drawn to a method for identifying a compound which modulates the activity of the polypeptide of Invention II, classified in class 435, subclass 26.

VII. Claim 15, drawn to a method for identifying a compound which modulates the activity of the polypeptide of Invention II, wherein a host cell

comprising an expression vector that expresses said polypeptide is used, classified in class 435, subclass 252.3.

VIII. Claim 16, drawn to a method for identifying a compound which binds to the polypeptide, classified in class 435, subclass 26.

IX. Claim 17, drawn to a composition comprising an agent identified by the method of Invention VIII, classified in class 514, subclass 789.

X. Claim 18, drawn to a method for treating or preventing a disease with the agent of Invention IX, classified in class 514, subclass 789.

XI. Claim 19, drawn to a method for identifying an agent which modulate the activity or expression of the polypeptide, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

The products groups I-III and IX are patentably distinct inventions because groups I and II are drawn to polypeptides, group III is drawn to a polynucleotide and group IX is drawn to composition comprising an agent, which encompasses inorganic or organic compounds.

The polynucleotide of group III and polypeptide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the

encoded polypeptide. While a polypeptide of Group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group III, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and III are patentably distinct.

Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of groups I and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Searching, therefore is not coextensive.

The polypeptide of group I and the antibody of group II are patentably distinct for the following reasons:

While the inventions of both group I and group II are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group II encompasses antibodies. Thus the polypeptide of group I and the antibody of group II are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group II is dependent upon the correlation between the scope of the polypeptides that the antibody

binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group I is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group II is defined in terms of its binding specificity to a small structure within SEQ ID NO: 2. Thus immunization with the polypeptides of group I would result in the production of antibodies outside the scope of group II.

Furthermore, searching the inventions of group I and group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group II. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group II are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group III and the antibody of group II are patentably distinct for the following reasons. Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and

polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group III will not encode an antibody of group II, and the antibody of group II cannot be encoded by a polynucleotide of group III. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group III would impose a serious search burden since a search of the polynucleotide of group III is would not be used to determine the patentability of an antibody of group II, and vice-versa.

The polypeptides of groups I and II and the polynucleotide of group III and the agent of group IX are unrelated because the product of group IX encompasses compounds, both inorganic and organic, that are unrelated to the products of groups I-III.

Invention I and Inventions IV, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of group I can be used for the production of antibodies against the protein. Searching the inventions of groups I, IV, VI and VIII together would impose serious

search burden. The inventions of groups I, IV, VI and VIII have a separate status in the art as shown by their different classifications. Moreover, even if the polypeptide product were known, the methods of groups IV, VI and VIII may be novel and unobvious in the view of the preamble or active steps.

Inventions III and Inventions V, VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention III can be used for the production of the protein of group I or in hybridization assays. Searching groups III, V, VII and XI together would impose serious search burden. Groups II, V, VII and XI have a separate status in the art as shown by their different classifications. Moreover, even if the polynucleotide product were known, the method of groups V, VII and XI may be novel and unobvious in the view of the preamble or active steps.

Invention IX and Invention X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, such as performing binding assays. Searching groups IX and X together would impose serious

search burden. Moreover, even if the agents were known, the method of group X may be novel and unobvious in the view of the preamble or active steps.

Inventions IV-VIII and X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different function or different effects. (MPEP 806.04, 808.01). The instant specification does not disclose that these methods would be used together. The method of using a polypeptide, method of using inorganic or organic compounds and the method of using a polynucleotide or cell comprising said polynucleotides are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Therefore, the method of groups IV-VIII and X-XI are divergent in materials and steps. Further, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search groups IV-VIII and X-XI together.

Inventions IV, VI and VIII are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search groups IV and VI-VII together.

Inventions V, VII and XI are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in

steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search groups V, VII and XI together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Yong D. Pak
Patent Examiner 1652